GRAIN MILLERS

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April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: Docket N. 02N-0278, Proposed Rulemaking "Prior Notice of Imported Food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002"

To Whom It May Concern:

Grain Millers, Inc. (GMI) appreciates the opportunity to comment on the Food and Drug Administration's (FDA) proposed regulations of prior notice of imported food under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (a.k.a. The Bioterrorism Act). After the tragic events of September 11, 2001, protecting the United States public has never been more important and regulatory actions have lead to a significant increase in security. GMI supports this focus on increased security and the need to better protect the U.S. food supply and food imports against the potential for terrorist attack.

GMI is a privately held company and operates three oat mills in North America; two in the US and one in Canada. We also own and operate a large scale packaging facility producing tubes of oatmeal and flavored Instant oatmeal for consumers in the US as well as a smaller scale facility in Canada. Additionally, we own and operate two dry mix facilities, a dairy operation, produce and market a broad line of certified Organic consumer products as well as operating grain and animal feed ingredient trading operations. As such, we have a vested interest in not only maintaining a safe domestic food supply, but also a keen interest in maintaining secure and open borders to facilitate trade.

GMI (and all other users and processors of oats) is especially concerned about any undue restrictions on the free trade of oats from Canadian farmers and elevator companies. In 2002, production statistics from the USDA indicate that U. S. production of oats dropped to the lowest level seen *since before the Civil War.*

02N-0278 C189

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Due to the extremely limited production of domestic oats, US oat millers are forced to purchase in excess of 90% of their annual production requirements (approximately 130,000,000 bushels) from abroad, most notably from Canada, Finland and Sweden. It is of utmost importance to the oat milling industry that this international oat trade not be unduly restricted through the implementation of this new regulation.

FDA's proposed regulations concerning Section 307 of the Bioterrorism Act provides for additional food security but does not consider the impact on trade as mandated by Congress within the legislation. As currently proposed, the regulation for prior notice of imported foods will likely enhance the safety of food imported into the United States but will undoubtedly inhibit and, perhaps, prohibit trade with foreign countries. GMI believes that the proposed regulations for prior notice should be amended in several ways to better facilitate commercial trade and that such amendments can be accomplished without sacrificing the intent of the legislation, protecting the safety and security of the imported food supply.

The following are GMI's major points of concern that should be addressed in FDA's final regulation:

Allow option for exporter to submit a prior notice

The Bioterrorism Act, as passed by Congress, does not specify what entity must submit the prior notice, only that it must be submitted prior to arrival at the anticipated port of entry. Under the proposed regulations, FDA has limited the group of entities that can submit prior notice. The entities are limited to a purchaser or importer of an article of food who resides or maintains a place of business in the United States or an agent who resides or maintains a place of business in the United States acting on behalf of the U.S. purchaser or U.S. importer. FDA states it will also allow submission by a customs broker/filer if it is the U.S. agent of the U.S. importer or U.S. purchaser.

Despite FDA's stated intent to create "less confusion" and "greater compliance," GMI believes that by excluding the exporter from the list of those permitted to submit prior notice, the FDA is making it extremely difficult and time consuming for companies to comply with the prior notice regulation. In most situations, the exporter already has direct access to the required information since much of it is already required for customs notification. The exporter, therefore, will be able to more quickly and effectively execute the prior notice. By requiring the prior notice to be submitted by the importer or purchaser, FDA is creating a "middle-man" where none is necessary and subsequently adding more confusion and possibly delay into the system.

Furthermore, in the normal flow of commerce, the information needed to update a prior notice with current arrival date and time data will normally flow from the carrier to the shipper/exporter. Requiring the importer to submit the notice and updates will only make the process more cumbersome as the exporter will possess the information and be in the best position to monitor the progress of each shipment and submit timely updates.

None of the reasons FDA provides to explain why the submitter must have U.S. residency are significant enough to outweigh the advantages of including the exporter as an approved submitter. A variety of options should be available for submission of the prior notice since FDA will maintain jurisdiction over the article of food and right of refusal at the border if prior notice is not received. Flexibility regarding the submitter will leave both the choice and responsibility in the purview of the commercial sector that will determine the most efficient and effective entity to submit the prior notice. The need for U.S. residency in order to conduct audits is also unnecessary since U.S. purchasers could simply be required to maintain records of all prior notices for food imports subject to FDA inspection, making it a matter of administrative record keeping and not unnecessary information shuffling.

Left unchanged, GMI believes that the FDA proposed rules for the prior notice requirement will adversely affect competition, in stark contrast to the directly stated goals of Congress. In many cases, U. S. buyers will attempt to avoid the hassle of dealing with the prior notice issue entirely and seek to source their needs from only U. S. based facilities. This will restrain trade and unduly penalize non-domestic suppliers. GMI strongly believes that allowing exporters to meet the prior notice requirements places the responsibility where it belongs; i.e. in the hands of marketplace to decide who is in the best position to meet the prior notice requirements.

Time period for submission of prior notice

Section 307 of the Bioterrorism Act requires that the notice be provided by a specified period of time in advance of the time of the importation. The Act goes on to clarify that the required time of submission "may not exceed five days" and sets a minimum default time of eight hours if final regulations are not established by December 12, 2003.

Under the Act, FDA was given a clear window in which to establish a specified period of time and the flexibility to consider several different factors when determining the period of time; such as the effect on commerce, the modes of transportation, and locations of ports. However, the proposed regulation does not appear to take into consideration any of these very important factors. Instead, FDA claims that "noon of the calendar day before the day the article arrives at the border crossing" is the time necessary for it to receive, review and appropriately respond to a notice.

Need for 24/7 staffing

GMI believes that FDA has established a period of time that is both impractical and unnecessary. FDA is within the mandates of the Act to establish this period of time; however, such an extended period of time should be unnecessary if the FDA is truly concerned about receipt, review, and response without limiting the free flow of commerce.

According to the regulations, submission and receipt will be completely electronic and, therefore, instantaneous. A review process will likely take a longer period of time, but FDA already possesses the basic structure of a successful and expedient review process under OASIS. Modifications to the OASIS procedure, if not directly to the system, could greatly reduce the time needed for review.

The last and most critical reason that FDA points to as a basis for establishing the calendar day before arrival requirement is the need to "ensure it can plan and that its staff can travel to the arrival point" in response to a notice. To address this concern, the FDA should not put additional time into the process, thereby restricting commerce, but rather consider better utilizing the resources available to it. In order to have an effective prior notice system, FDA will have to allocate resources such that there will be staff available twenty-four hours a day, seven days a week (24/7), throughout the year at every port of entry for receipt, review, and response. How to accomplish 24/7 staffing at every port is a decision for FDA, but GMI believes that it is possible by working with U.S. Customs or through the hiring of more inspectors as authorized under the Bioterrorism Act. These actions should be taken first before unnecessary and costly regulations are promulgated.

The FDA specifically states that there is little concern on their part for regulations that are perceived by industry as merely inconvenient or burdensome. This implies that there is also little concern on the part of the FDA for the financial impact of the regulations. However, failing to staff ports of entry 24/7 will drive up the cost of transportation to such astronomical levels as to be unconscionable on the part of the FDA. Truck traffic must be allowed to flow through the borders as seamlessly as possible.

Consideration of modes of transport and shorter submission deadline

An additional concern that the proposed period of time raises is the restriction that is placed on short lead-time shipments. The proposed regulation does not differentiate between various modes of transportation such as air, rail, truck, and sea.

By applying a one size fits all time period for all modes of transportation, the FDA has indirectly inhibited cross-border trade that, in many cases, relies on same-day or immediate shipping. These shipments are not confined to businesses dealing in "catch of the day" transactions as appropriately identified by FDA, but also involve many food industries that rely on same-day shipments on a routine basis where customers are mere minutes from the Canadian or Mexican border. Same-day cross-border shipments typically involve transport by truck or rail, and thus the unnecessary impediment to trade could effectively be reduced by adjusting the period of time for prior notice based on different modes of transport.

Sea carriers will traditionally have more time then rail, truck or air carriers and, therefore, should be considered separately. Time periods for these other modes of transportation could be significantly reduced without sacrificing security if FDA establishes 24/7 staffing as suggested above.

The proposed four hour window for arrival at the border may be sufficient for either sea or air transportation but may be too narrow for truck shipments and is definitely too narrow for rail shipments. There simply is no mechanism available on rail shipments to provide FDA with anticipated arrival time at the border point within a four hour window. Rail carriers do not have the capability to provide this information with any degree of accuracy. FDA must readdress this window for rail shipments, recognize the inherent limitations, and provide a much broader window for rail shipments.

An additional consideration is the impact the long lead notice requirement will have on the number of amendments and updates that will be required under the regulations as currently proposed by FDA. As written, truck shipments of bulk commodities will require an update or amendment 100% of the time. Final weight on these shipments is never available until loading has been completed. Given the short transit time for these shipments to the port of entry, an amendment or an update to adjust the quantity will need to be processed for every shipment.

GMI also contends there is a practical reason to shorten and better specify the time period for prior notice. As written, the current proposal of noon the calendar day before arrival will cause delays in the receipt, review, and response by FDA, delays at the border, and confusion regarding the time of arrival.

Under the regulations as proposed, the reality is that the "noon the day before" time period will lead to the submission of the majority of prior notices by 11:59 a.m. and will, subsequently, mean the arrival of a large number of trucks at the given port of entry at 12:01 a.m. of the next day. Conversely, if a submission is received at 12:01 p.m., the shipper must wait until 12:01 a.m. the day after next; a delay of nearly 36 hours! This provides an unclear and undesired window of either 12 or 36 hours before entry is possible and will lead to an inevitable "bunching" of submissions at noon and of vehicles at midnight every day.

The solution is for the FDA to simply follow the default minimum time period established by Congress in the Bioterrorism Act of 8 hours prior to arrival at the border. A shorter, specified minimum time period will facilitate a more regular flow of submissions, decrease the need for amendments and updates and reduce restrictions on same-day shipments.

Clarification of requirement for specifying grower "if known"

The Bioterrorism Act specifies that several items must be provided in any prior notice including the grower of the article, if known, within the specified time period. The FDA is proposing to require the submission of the identity of "all growers of each article and the growing location if different from the grower's business address, if known at the time of submission of the prior notice." The regulations go further to require identification of the growers if discovered between the time of first submission and amendment. The proposed regulation also requires the identification of all growers if a product is sourced from more than one grower, if known.

This "grower, if known" requirement needs to be clarified to address the inherent trade practices for bulk grain products that are typically sourced from grain storage facilities that co-mingle grain from many different growers. The practice of mixing and blending grain is common in the grain storage and handling industry and poses a major problem for complying with the regulations as proposed by the FDA. These facilities may, in some cases, possess the names and locations of the growers that it purchases grain from, but they do not maintain records on which farmer's grain was sold to which customer. Such a system does not exist for the majority of the bulk grain in commerce today and, in the few cases where the identity is preserved, there is a significant premium associated with the service.

FDA's expectation that all bulk grain shippers identify all possible growers, if "known" to some degree, puts an undue and useless burden on the submitter. The information is of no practical use since it cannot truly help determine the actual grower of a single lot of grain (which may be as small as a few hundred bushels) co-mingled within a shipment of 100 cars of grain (which may be as large as 500,000 bushels). A better alternative is for FDA to provide flexibility in the definition of "if known" by requiring the submitter of the notice to identify the grower only when a direct connection to the production of the article and a specific shipment can be clearly established.

If the actual grower of an article needs to be determined, in the case contamination, the FDA can and should use the information collected under Section 305 of the Bioterrorism Act, Registration of Food Facilities, to locate the grain storage facility and subsequently the growers associated with that facility.

FDA inspections at the port of entry

The implementation of the prior notice regulation significantly increases the likelihood for inspections to occur on food articles at the port of entry. In the process of inspecting trucks or rail cars, it may be necessary for the inspector to break several tamper resistant seals that are put on the vehicle by the shipper to provide additional security. From previous experience, it is widely known that these seals are not always replaced by the inspector and can cause the exporter to incur significant, avoidable additional costs in the form of rejections once the shipment reaches the purchaser as seal integrity is now scrutinized by nearly all receivers of food products and/or ingredients.

Though the procedure for the resealing of rail cars and trucks after inspection is not addressed in the Bioterrorism Act, GMI feels very strongly that FDA should establish a set of standard procedures for the inspection of truck and rail cars that explicitly states the responsibility of the inspector to replace all seals removed by the inspector, document the resealing and provide the information, including seal numbers, to the exporter. A standard procedure described in the final regulations will help to reduce problems with loss and liability after implementation and help to secure the food once in the U.S. Furthermore, failure to follow the defined procedures should result in liability on the part of the FDA.

Additional Concerns

GMI would also like to express additional concerns regarding the proposed regulations that should be addressed subsequent to the changes outlined above.

- What will be the disposition of a single car of grain from a unit train if the FDA chooses to deny entry to the single car? What happens to the balance of the train?
- Will unit train shipments (50-100 cars) require a single notice or a notice for each car? If the notice is for each car, the process will require an amendment or update for the quantity loaded into each car.
- Will rail shipments that originate in the U. S., consigned to U. S. destinations but routed through Canada for Railroad convenience require a prior notice as an "import?" Has this traffic been considered by the FDA?
- What will be FDA's role in the new border security bureau under the Department of Homeland Security?
- Is the prior notice requirement in compliance with NAFTA and WTO agreements?
- How will the liability for cargo that is inspected and subsequently held at the port of entry be determined?
- Will FDA truly be capable of handling the number of prior notices that will be submitted under the new system? While FDA has estimated a flow of approximately 20,000 notices per day, has FDA considered that most notices will have amendments and numerous updates to meet the requirements? This volume could easily double or triple the estimate when amendments and updates are considered.

Conclusion

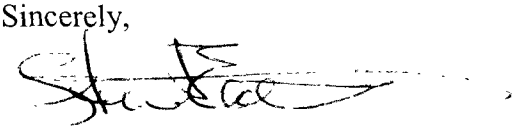
FDA's proposed regulations implementing Section 307 of the Bioterrorism Act accomplish the intent of the legislation in the most restrictive and commerce restricting manner possible. The flexibility that was intentionally added to the Bioterrorism Act to make it possible to protect the U.S. food supply and, at the same time, not unduly restrict foreign trade does not appear in these proposed regulations. The FDA must change several provisions in the final regulations if it is to provide both effective food safety at the borders and facilitate the continuation of robust international trade.

GMI again strongly suggests the following changes be made:

- Allow the exporter to submit prior notice.
- Provide 24/7 staffing at the ports of entry
- Make the period of time for submission shorter and better defined for different modes of transportation.
- Clarify the grower "if known" requirement.
- Determine procedures for the resealing of inspected shipments.

GMI appreciates the opportunity to provide comments to FDA on its proposed regulations and we look forward to working with the agency in developing a prior notice system that is both effective and will continue to facilitate international trade. If you have any questions about these comments or would like further information please contact Rick L. Schwein or Kris Nelson at (952) 829-8821.

Sincerely,



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